

Application No.: 10/781,589  
Art Unit 3766

### REMARKS

Claims 1, 13, 14, and claims 122-126 are pending and rejected pursuant to the final Office Action. Herewith no claims are canceled, claims 1, 14, 122, and 124-126 are herewith amended and no new claims are added.

This response is intended to place the application in condition for allowance without introducing new issues or requiring additional searching.

Applicant respectfully requests entry and favorable consideration of the amendments and remarks tendered herewith.

#### Objections to the Specification and Prior Amendment

The specification is objected to due to a parent application cross-referenced that has since matured into U.S. Letters Patent. Applicant herewith amends the first paragraph of the application to recite the patent number.

The specification is also objected to as failing to provide proper antecedent basis for the claimed subject matter; namely, "plurality of radial forces," and "fourth segment." Applicant respectfully disagrees and refers to several passages and drawings of the application as-filed describing how a vast number of different amounts of stiffness and directional bending forces can be designed and fabricated according to the present invention. For example, please see the Summary portion (e.g., paragraph number 0013 – excerpted in part, below) and drawings 8A and 8B (and accompanying text). Parts of the accompanying text is reproduced immediately below:

[0071] Referring now to FIGS. 8A and 8B, there are shown in cross-section lead body 12 exhibiting symmetric equal bending stiffnesses around each axis of bending in FIG. 8A and lead body 12 having asymmetric unequal bending stiffnesses around each axis of bending in FIG. 8B. Thus, lead 10 shown in FIG. 8A may be bent in any direction from 0.degree. to 360.degree. without any change in bending moment being required. Contrariwise, lead 10 shown in FIG. 8B requires more bending moment when lead 10 is bent in the directions of 0.degree. and 180.degree., while less bending moment is required when lead 10 is bent in the 90.degree. and 270.degree. directions. (emphasis added.)

The last amendment filed is objected to under 35 U.S.C. §132(a) for allegedly introducing new matter into the disclosure. As mentioned above (and repeated below) the segments numbered 2 and 4 in the disclosure are not the same but rather the

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numbering was used to show that a relatively stiff and flexible segments. And the drawings clearly depict certain illustrative embodiments wherein each segment is different from each other. Thus, the convenient term or phrases should not be viewed as limiting the scope of the invention which clearly describes and depicts multiple segments (and Applicant can not find any words or clear disclaimer or disavowal limiting the number of segments that can utilize and benefit from the teaching of the present invention).

**Rejection under 35 U.S.C. §112**

Claim 13 is rejected under §112, first paragraph, as allegedly failing to comply with the written description requirement. Applicant respectfully traverses said rejection.

In addition, the foregoing remarks are hereby incorporated by reference in response to the rejection of claim 13 (at paragraph 8 of the instant final Office Action) which response specifically alleges fully traversal of said rejection of claim 13.

Accordingly, Applicant respectfully declines to cancel any of the alleged new matter in the instant reply to the final Office Action.

Claim 126 is rejected under §112, second paragraph for allegedly being indefinite for failing to particular point out and distinctly claim the subject matter Applicant regards as the invention. While Applicant disagrees with the rejection the phrase has been amended to provide sufficient antecedent basis for the claim limitation.

**Claim Rejections under 35 U.S.C. §102**

Claims 1, 13, 14 and 122-126 are rejected as allegedly anticipated by the '897 patent to Rutten et al. (Rutten).

Applicant respectfully traverses this rejection. As noted by the Examiner the sole inventor of the instant application is a named co-inventor of Rutten. Applicant hereby asserts that Rutten does not represent prior art *vis-à-vis* the instant application as any invention disclosed but not claimed in Rutten was derived from the inventor of the instant application and thus is not the invention "by another."

The foregoing notwithstanding, Applicant respectfully asserts that Rutten does not include *each and every claim limitation recited* in claims 1, 13, 14 and 122-126. For example, Rutten does not appear to contemplate, disclose or include the notion of a

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preconfigured radially-directed bending stiffness characteristic in contrast to the presently claimed invention.

Note that the application-as-filed includes the following passages (from paragraph 0013):

(c) a medical electrical lead which owing to variations in bending stiffness along its axial direction imparts a positive tip force or a forward driving force to the lead, and where bending of the lead may preferentially take place along different pre-determined bending planes (e.g., three dimensional bending along multiple preferred orientations); (d) a pacing or defibrillation lead wherein variations in bending stiffness are rotationally symmetric; (e) a pacing or defibrillation lead wherein bending stiffness is rotationally asymmetric to permit orientation of one or more electrodes, fixation means, or other lead features relative to the bending plane of a bent or curved section; (emphasis added.)

And from paragraph 0062:

[0062] In accordance with some embodiments of the present invention, lead may be configured to have one relatively stiff portion 2 adjoining a relatively flexible portion 4, or may have a series of alternating relatively stiff portions 2 and relatively flexible sections 4. The bending stiffness of adjoining sections may increase or decrease in step-wise fashion, or may increase or decrease monotonically, exponentially or logarithmically. The respective lengths of relatively stiff portions 2 and relatively flexible portions 4 may also be varied according to the particular venous anatomy in which lead 10 is to be implanted.

Thus, Applicant respectfully traverses the merits of the rejections posed in the final Office Action; however, they are believed to be rendered moot by the above amendments.

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**Conclusion**

The application is in condition for allowance and notice of the same is respectfully requested.

Respectfully submitted,

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